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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/487, 701 06/07/95 GRAY

J 028723-020

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EXAMINER

MARSCHEL, A

ART UNIT	PAPER NUMBER
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1631

54

DATE MAILED:

04/17/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>08/487,701</b>	Applicant(s) <b>Gray et al.</b>
	Examiner <b>Ardin Marschel</b>	Group Art Unit <b>1631</b>

Responsive to communication(s) filed on Feb 2, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claim

Claim(s) 48, 49, 51-69, 71-74, 76-86, 88-93, and 95-104 is/are pending in the application.

~~Claims~~,  Claim(s) 1-47, 50, 70, 75, 87, and 94 have been canceled. ~~Claims withdrawn from consideration~~

Claim(s) 98-101 is/are allowed.

Claim(s) 48, 49, 51-63, 65-69, 71-74, 76-86, 88-93, 95-97, and 102-104 is/are rejected.

Claim(s) 64 is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

**-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --**

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 2/2/00, have been fully considered but they are not persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the first sentence of the specification following the title. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Specifically certain applications listed in the priority statement have become abandoned but are not listed as such therein.

Claims 48, 49, 51-63, 65-69, 71-74, 76-86, 88, 90-93, 95, and 96 are rejected under 35 U.S.C. 112, first paragraph, as

containing subject matter which was not described in the specification is such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. NEW MATTER in the claims is directed to a complexity of 40 kb as given in claim 48, line 3, for example, plus other claims. This rejection is reiterated and maintained from the previous office action, mailed 9/22/99. Consideration of the citations pointed to by applicants revealed no specific complexity citation regarding the probes as claimed. These citations do not specifically list a "complexity" of probe as 40kb. For example, at page 13, lines 6-7, the prior art is discussed and not what is intended for the instant probe complexity. At page 37, lines 24-26, the target sequence is described which neither discloses complexity nor probe characterization. The page 38, lines 5-13, citation describes a probe of about 40 kb without defining this as complexity. It is noted that complexity and length are not identical concepts since the complexity is different in number due to accounting for repetitive sequences therein. Length, however, is length without such repetitive sequence compensation as to what is meant.

Claim 74 is rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is noted that claim 74 requires the presence of "morphologically identifiable chromosome" in line 2. This limitation has been removed from claim 72 thus making the presence of this in claim 74 conflict with claim 72 which requires interphase chromosomal material as the target. This rejection is necessitated by amendment.

The following is a quotation of 35 U.S.C. §.103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Weissman et al. (P/N 4,710,465), taken in view of Lichter et al. [PNAS, Vol. 85, pp. 9664-9668 (1988)] (both already of record).

This rejection is reiterated and maintained from the previous office action, mailed 9/22/99, and as necessitated by amendment regarding newly added claims listed above as rejected. Applicants firstly argue that the probe complexity of the instant claims are not given in the combination of references. In response it is noted that the probes of Weissman et al. are made up of unique segments as discussed in the previous office action. Probe complexity equals probe length if there is no repetitive segments in the probe. Thus, the probe range of lengths as noted previously of the reference being 50 kb to 2000 kb clearly encompass large portion of the instant claim complexity range and thus suggest common species of probe practice. Additionally, Licher et al. noting that signal is enhanced at lower probe lengths does not negate the reference also describing the usability of probe of longer lengths. In summary, the rejection is still deemed to be proper.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 125 of copending application Serial No. 08/473,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because the probe type in said claim 125 is generic with regard to type and unique sequence probes are most commonly the probe type utilized in the hybridization art thus making that specie of probe well known within generic probes types as in said claim 125 thus suggesting and motivating the unique probe type in the instant claim practice. The various abnormalities of the instant claims are also extremely well known chromosomal abnormalities that are assessed by hybridization assay. It is also noted that the method of said claim 125 starts with staining as the first step and ends with the obvious indicative practice step which is motivated by staining as an obvious step. Otherwise, why stain at all? Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as as necessitated by amendment regarding newly added claims listed above as rejected.

This is a *provisional obviousness-type double patenting* rejection because the conflicting claims have not in fact been patented.

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 48, and 50-58 of copending application Serial No. 08/477,316. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of staining utilizing unique sequence high complexity probes. The instant claims include any chromosome whereas the specific chromosomes of 08/477,316 are clearly species therein. The various abnormalities of the instant claims are also extremely well known chromosomal abnormalities that are assessed by hybridization assay. Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as necessitated by amendment regarding newly added claims listed above as rejected.

This is a *provisional obviousness-type double patenting* rejection because the conflicting claims have not in fact been patented.

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are

provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 48-50 of copending application Serial No. 08/487,387. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of staining utilizing unique sequence high complexity probes. The instant claims include any chromosome whereas the specific chromosomes and well known components therein, such as paracentric regions, of 08/487,387 are clearly species therein. The various abnormalities of the instant claims are also extremely well known chromosomal abnormalities that are assessed by hybridization assay. Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as necessitated by amendment regarding newly added claims listed above as rejected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 62-65 and 125-148 of copending application Serial No.

08/478,740. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of staining utilizing high complexity probes. The instant claims include generic sample sources including fetal DNA which clearly includes specific fetal DNA sample of 08/478,740 as species therein. See the fetal limitation in instant claim 76. The various abnormalities of the instant claims are also extremely well known chromosomal abnormalities that are assessed by hybridization assay. Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as as necessitated by amendment regarding newly added claims listed above as rejected.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-33 of copending application Serial No. 08/472,312. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of staining utilizing unique sequence

high complexity probes. The instant claims include any chromosome whereas the specific chromosomes of 08/472,312 are clearly species therein. The various abnormalities of the instant claims are also extremely well known chromosomal abnormalities that are assessed by hybridization assay. Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as as necessitated by amendment regarding newly added claims listed above as rejected.

This is a *provisional obviousness*-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 72, 74, 76-86, 88-93, 95-97, and 102-104 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 131, 132, 144-147, and 150-153 of copending application Serial No. 08/487,974. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to methods of staining utilizing unique sequence high complexity probes. The instant claims include any chromosome whereas the specific fluorescent labeling of 08/487,974 are clearly species therein. The various abnormalities of the instant claims are also extremely well known

chromosomal abnormalities that are assessed by hybridization assay. Lastly the complexity is high in both sets of claims and clearly overlap regarding complexity of probe practice. This rejection is maintained and reiterated from the previous office action, mailed 9/22/99, as as necessitated by amendment regarding newly added claims listed above as rejected.

This is a *provisional obviousness*-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 64 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 98-101 are allowed.

Applicants' amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL.** See M.P.E.P. § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

This application is subject to the provisions of Public Law 103-465, effective June 8, 1995. Accordingly, since this application has been pending for at least two years as of June 8, 1995, taking into account any reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), applicant, under 37 CFR 1.129(a), is entitled to have a first submission entered and considered on the merits if, prior to abandonment, the submission and the fee set forth in 37 CFR 1.17(r) are filed prior to the filing of an appeal brief under 37 CFR 1.192. Upon the timely filing of a first submission and the appropriate fee small entity under 37 CFR 1.17(r), the finality of the previous Office action will be withdrawn. In view of 35 U.S.C. 132, no amendment considered as a result of payment of the fee set forth in 37 CFR 1.17(r) may introduce new matter into the disclosure of the application.

If applicant has filed multiple proposed amendments which, when entered, would conflict with one another, specific instructions for entry or non-entry of each such amendment should be provided upon payment of any fee under 37 CFR 1.17(r).

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technical Center receptionist whose telephone number is (703) 308-0196.

April 14, 2000

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER